

P20918.A03


REMARKS

The Examiner is respectfully requested to enter the foregoing amendment prior to examination of the above-identified patent application.

Applicant notes that the claims have been amended strictly to ensure closer compliance with U.S. patent practice and not for a reason related to patentability or for a reason related to distinguishing the invention over any known prior art reference.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed number.

Respectfully submitted,  
Fred ZACOUTO et al.

  
Reg. No. 28,394

Neil F. Greenblum  
Reg. No. 28,394

February 28, 2002  
GREENBLUM & BERNSTEIN, P.L.C.  
1941 Roland Clarke Place  
Reston, Virginia 20191  
(703) 716-1191

Attachment: Appendices 1-5

**APPENDIX 1**

*Changes to the paragraph between lines 4-8 on page 7 of the specification:*

This valve can initially be closed during the formation of the callus. Thus the implant is perfectly rigid and behaves like a classic screw. The valve is then opened so that the implant functions according to the invention, with its shock-absorbing function. A valve with a progressive opening [makes] also makes it possible to provide the function for adjusting the coefficient of resistance.

**APPENDIX 2**

*Changes to the paragraph between lines 13-18 on page 20 of the specification:*

For example, the invention can provide implants of this type with which it is possible to impose symmetrical movements of rotation, that is to say in the same direction and of the same value of rotation, of the pedicle screws or similar anchoring means of the two individual implant [elements] parts, or, by contrast, antisymmetrical movements, that is to say in opposite directions, or else independent of one another.

**APPENDIX 3**

*Changes to the paragraph between lines 30-34 on page 20 of the specification:*

The skeletal implant has a first and a second part or end element, means for anchoring in bone parts, which means are connected respectively to the said first and second end elements, at least one deformable element connected respectively to the said first and second anchoring means, and means permitting a nonrectilinear movement, particularly a rotation, between the said anchoring means.

#### **APPENDIX 4**

*Changes to all of the paragraphs beginning on line 1 of page 29 and ending on the last line of page 29 of the specification:*

Fig. 48 shows a possible implantation of the invention on a spine;

[- Fig. 49 [is] shows an electrical wiring diagram of the control of an implant according to the invention;

[- Figure 51] Fig. 50 shows a diagrammatic view of a pair of implants for antisymmetrical rotations according to a first embodiment of the invention[.];

[- Figure 52] Fig. 51 shows another embodiment of such a pair of implants[.];

[- Figure 53] Fig. 52 shows another embodiment of such a pair of implants[.];

[- Figure 54] Fig. 53 shows one particular embodiment of an implant from [Figure 53,] Fig. 52;

[- Figure 55] Fig. 54 shows a view of a pair of implants according to the invention for symmetrical rotation movements according to a first embodiment[.];

[- Figure 56] Fig. 55 shows a second embodiment of such a pair of implants[.];

[- Figure 57] Fig. 56 shows a third embodiment of a pair of implants for symmetrical rotations[.];

[- Figure 58] Fig. 57 shows a view of an embodiment of an implant from [Figure 57,] Fig. 56;

[- Figure 59] Fig. 58 shows a diagrammatic view of a pair of implants, one of which permits a simultaneous axial and rotational movement in a plane transverse to the general direction of the implant[.];

[- Figure 60] Fig. 59 shows a diagrammatic view of a pair of implants, one of which permits a rotation without translation movement, in a plane perpendicular to the general direction of the implant[.];

[-Figure 61] Fig. 60 shows a side view of an embodiment of an implant according to [Figure 59,] Fig. 58;

[-Figure 62] Fig. 61 shows a front view with partial sectioning of this implant[.];

[-Figure 63] Fig. 62 shows a front view, with partial sectioning, of an implant according to an embodiment from [Figure 60,] Fig. 59; and

[-Figure 64] Fig. 63 shows a cross section of a detailed embodiment of the invention.

[In Figures 51 to 60 which follow, it is assumed that the spine extends in a vertical direction and that the two individual implants are arranged on either side of the succession of spinous processes, and that the lower pedicle screws are screwed into a first vertebra and the upper pedicle screws are screwed into another vertebra, which may or may not be adjacent and is arranged above the first one. The two individual elements are shown in a frontal plane which is the plane of the drawing. The result of this is that the pedicle screws

P20918.A03

should be oriented in a more or less sagittal plane, in other words more or less perpendicular to the plane of the drawing, or at any rate inclined, but for reasons of simplicity of representation they have been shown in the same frontal plane. Likewise, the joining elements have been shown in the same frontal plane, whereas they should be in the perpendicular or inclined plane which contains the pedicle screws.]

**APPENDIX 5**

*Changes to the second full paragraph on page 31 of the specification:*

Figs. 2 through 6 show an application of the principle explained in reference to Figs. [1 an] 1a and 1b.

**APPENDIX 6**

*Changes to the third full paragraph on page 32 of the specification:*

The screw 103 is position in a known way, but such that its middle part 108 is disposed at the level of the fracture. Moreover, the screw is immobilized in axial rotation in such a way that the plane of the blade 110 is perpendicular to the plane of Fig. 2, in a way that can produce a relative rotation of the parts 105 and [105] 106 of the screw around an axis perpendicular to this plane and passing through the level of the part 108.



**APPENDIX 7**

*Changes to the third full paragraph on page 33 of the specification:*

The chambers 220 and 221 are filled with a hydraulic fluid and connect through a calibrated opening 229 cut into the bottom [229] 227 of the cupel 225 and opening into the cylinder 226. Thus, when a compressive stress is exerted on the cupels 224 and 225 of the chamber 220, tending to push them toward one another, the volume of this chamber decreases while the fluid passes through the opening 229 and is forced into the chamber 221, whose volume increases. The force which opposes the approach of the cupels 224 and 225 is proportional to the approach speed, assuming that the bellows do not exert any force, particularly of an elastic nature.

**APPENDIX 8**

*Changes to the second full paragraph on page 34 of the specification:*

Moreover, a beaded chain 243 is engaged in the annular space 244 delimited by the fold of the bellows 222, which includes the edge of the cupel 224, and the bottom of the ring 241. The beads of the chain in this case have a diameter substantially equal to the distance at equilibrium between the edges of the cupels 224 and 225 which face one another. One end 245 of this chain exits the annular space [224] 244 through a slot 246 formed in the lateral wall of the stop ring 241, opposite the shoulder 242.

## **APPENDIX 9**

*Changes to all of the paragraphs beginning with the second full paragraph of page 56 and ending with the last paragraph of page 67 of the specification:*

In Figures 50 to 59 which follow, it is assumed that the spine extends in a vertical direction and that the two individual implants are arranged on either side of the succession of spinous processes, and that the lower pedicle screws are screwed into a first vertebra and the upper pedicle screws are screwed into another vertebra, which may or may not be adjacent and is arranged above the first one. The two individual elements are shown in a frontal plane which is the plane of the drawing. The result of this is that the pedicle screws should be oriented in a more or less sagittal plane, in other words more or less perpendicular to the plane of the drawing, or at any rate inclined, but for reasons of simplicity of representation they have been shown in the same frontal plane. Likewise, the joining elements have been shown in the same frontal plane, whereas they should be in the perpendicular or inclined plane which contains the pedicle screws.

[Figure 51] Fig. 50 shows two individual implants, a right-hand one and a left-hand one, generally designated by 1' and comprising a lower end rod 2' and an upper end rod 3' between which there is interposed a deformable hydraulic element 4' which has been shown in the form of a cylinder/piston assembly, but which in reality would instead be in the form of a metal bellows so as to prevent the escape of hydraulic liquid. Alternatively, this deformable element can be of the telescopic type or of an otherwise deformable type, for example a cylindrical cell which is elastic longitudinally but not transversely. The rods 2' and 3' are guided in the continuation of one another so as to move along the same vertical axis and to take up distanced or close positions as a function of the extent of filling of the deformable element 4'. The lower and upper ends 2', 3' have attachment means 5', 6' in the form of articulations. Extending parallel to the element 1' there is a rigid joining rod 7' which terminates in lower 8' and upper 9' attachment means in the form of articulations. The rod 7' extends essentially parallel to the individual element 1', but it could be more inclined, and can be made integral with this element, although this is not a requirement. Connected to each element 1' there is a lower pedicle screw 10' and an upper pedicle screw 11' whose threaded parts are fixed in the corresponding vertebral pedicles. The posterior end of the pedicle screws 10', 11' is received in the ends 5' and 6' in the manner of an articulation permitting an angular clearance at least in the plane constituted by the element 1' and the joining element 7'. If appropriate, the articulation can have a supplementary degree of freedom or can be of spherical shape giving a degree of freedom in rotation in all directions.

In an intermediate position, the screws 10', 11' are fixed and articulated respectively on the ends 8' and 9' of the joining element 7' by articulations also permitting an angular clearance in the common plane, for example the sagittal plane, of the element 1' and of its

joining element 7'.

The two deformable elements 4' of the pair of individual implants which form the complex implant shown in the drawing are connected via a line 12' on which there is arranged a hydraulic circuit element 13', shown in the example in the form of a slide valve.

The configuration shown in [Figure 51] Fig. 50 permits antisymmetrical rotation movements of the pedicle screws.

It is assumed that the pedicle screws have been screwed in the angular positions shown on the drawing, that the hydraulic circuits and the elements 4' are entirely filled with hydraulic liquid and that the valve 13' is in the closed position. In such a situation, the pedicle screws are blocked in their angular position shown on the drawing. In this position, the internal volume of the left-hand element 4' is smaller than that of the right-hand element 4', which corresponds to a more closed angle. If the valve is now opened, it will be appreciated that the pedicle screws are going to be able to pivot about the [centre] center of articulation of the points 8' and 9' at the end of the joining rod, as a function of the increase or reduction in the length of the corresponding element 1', itself dictated by the volume of liquid present in the associated deformable element 4'. Given the communication 12' between the two deformable elements 4', it will also be appreciated that any variation in the volume of liquid of one of the elements is compensated by an inverse variation in the volume of the other in such a way that the rotation of the pedicle screws in one direction on one of the elements is translated into a rotation of the pedicle screws in the other direction and having essentially the same absolute angular value.

This property can be made use of in various applications described in the above-mentioned EP and US applications.

If the hydraulic circuit element 13' is a viscoelastic regulating element which considerably brakes the passage of liquid, or prohibits this in the event of an abrupt angular movement of the pedicle screws, the vertebrae can be left free to pivot relative to one another in the frontal plane of the spine when the movements are slow, and, by contrast, the screws can be immobilized or their rotation considerably braked when the movements have a tendency to be rapid. In this way it is possible to obtain a damping effect in rotation while at the same time permitting a freedom of rotation for slow movements.

If the element 13' is an element with which it is possible to impose the supply of the hydraulic liquid into one of the deformable elements 4' and the withdrawal of the same volume of liquid from the other element 4', this supply then being followed by a closure of the communication, it is possible, some time after having implanted the two individual implants with given angles of pedicle screws, to initiate an external command, for example a transcutaneous magnetic command, in order to modify the angle and thereby to effect in small stages a correction of a vertebral deformation.

Means can be provided for exerting a continuous or intermittent constant pressure in

the bellows 4' in such a way as to permanently stress the skeletal parts whose position is to be corrected.

Of course, by using different hydraulic circuits, it is possible to achieve the two functions which have been described, as has been explained in the abovementioned applications.

Of course, according to the invention, it is also possible to use each individual implant with its joining rod as a totally independent element and to control each of the elements separately without any interconnection 12', in order to ensure some or all of the functions of modification of length and thus of angulation, as well as viscoelastic damping.

In a preferred manner, the implant element is also combined with a device with which it is possible to supply a deformable element 4' with high-pressure liquid, if this is necessary, from a deformable bellows functioning, for example, as a pump actuated by the body, as has been described by the abovementioned application. In the case of the use of two individual implants for forming a complex implant, as shown, this supply and discharge means can be common to both implants.

[Figure 52] Fig. 51 shows a complex implant similar to that [in Claim 1] already described herein, but in which the joining rods 7' are articulated at the free ends or heads of the pedicle screws while the deformable individual element is articulated in the intermediate position, this giving an inversion of the movement of rotation relative to that shown in [Figure 51] Fig. 50, and additionally moves the [centre] center of rotation of each pedicle screw rearwards.

[Figure 53] Fig. 52 shows a complex implant which is identical, for the individual implants 1', to that shown in [Figure 2] Fig. 2. By contrast, the joining element 7', which was a single rigid rod, has been replaced by a joining element 14' formed in the manner of an individual implant and thus comprising two ends 15', 16' which are capable of moving longitudinally relative to one another with interposition of a deformable hydraulic element 17', by which means it is possible to have a joining element whose length can be modified if necessary or which can itself have a damping effect analogous to that of the actual implant 1 if this function is present.

Preferably, the two elements 17' of the two individual implants shown are connected via a channel 18' with interposition of a hydraulic circuit element 19'.

The desired functions will then be determined by the nature and control of the hydraulic regulating elements 13' and 19' and it will be appreciated that in such a design it is possible, if so desired, to make the implant element 1' and its joining element 14' interchangeable and thus to fix the [centre] center of rotation of the pedicle screw either at the end 5' (or 6') or at the end 8' (or 9') or even at another point between these articulations.

[Figure 54] Fig. 53 is a diagrammatic representation of a practical embodiment of the device in [Figure 53] Fig. 52 (on which the lines and the hydraulic circuit elements 13', 17'

are not shown). The individual implant shown includes a hydraulic bellows 4' bearing on its upper face a component with an arm forming the rod 3', on its lower face a plate with an arm 2' forming the lower rod, the said rods having articulations 5' and 6' for the pedicle screws 10', 11'. The element 14' includes a hydraulic bellows 17' whose lower plate bears an arm 15' and the upper end an arm 16', the said arms bearing, at their free end, the articulations 8', 9' receiving the posterior ends of the screws 10', 11'. If appropriate, one arm of the element 1' and another arm of the element 14' can be mechanically secured or, by contrast, all these elements can be left independent, the link then being made only by the screws 10', 11'.

Thus, it is possible to arrange the bellows spatially one below the other and to form an implant according to the invention with a greatly reduced size.

In [Figure 55] Fig. 54, now, a device has been shown which is analogous to that in [Figure 1] Fig. 1, the only difference being that one of the deformable devices or bellows 4' has been replaced by a deformable device 20', which, furthermore can also be made in the form of a bellows and in which the points of attachment of the lower 2' and upper 3' arms have been inverted, in such a way that an increase in the volume of the device 20' entails, in contrast to the increase in volume of the device 4', a shortening of the implant element instead of a lengthening.

It is thus possible, by virtue of the interconnection via the line 12' and the element 13', to obtain symmetrical rotation movements instead of antisymmetrical rotation movements. In other words, the rotations of the screws 10', 11' on the right-hand side of the spine are identical to the rotations of the screws of the left-hand element, and of the same direction.

It is thus possible to obtain movements of flexion or extension of the spine this time in the sagittal plane.

As in the other cases, this can be made use of either to provoke a lordosis effect or vice versa, depending on the desired aim, for example by acting in stages from an external command, or to achieve a perfectly symmetrical damping effect in the case of spontaneous movement of rotation between the vertebrae, or else to achieve the two functions simultaneously by virtue of more complex circuits.

[Figure 56] Fig. 55 shows a configuration according to [Figure 55] Fig. 54, but in which the joining elements 7' are arranged, as in Figure 2, in such a way that the [centre] center of rotation of the pedicle screws is arranged at the ends of the screws.

Alternatively, it is also possible to combine the solution of [Figure 51] Fig. 50 and of [Figure 52] Fig. 51, placing the element according to [Figure 1] Fig. 1 on the right of the spine, for example, and an individual element according to [Figure 2] Fig. 2 on the left, it being understood that in this case the angular variations of the right-hand screws will at all times be the inverse of those of the left-hand screws, but of more different absolute value.

[Figure 57] Fig. 56 shows a complex implant which also permits symmetrical relations in the sagittal plane, as indicated in [Figure 56] Fig. 55, but in which the joining rod 7' of

each of the individual implants has been replaced by joining elements which are themselves of variable length, the one on the left being a joining element 14' as shown in [Figure 53] Fig. 52, while the joining element on the right also has an inversion of action in the area of the bellows. In other words, an arrangement is obtained in which the movements of rotation on left and right are symmetrical in the sagittal plane.

[Figure 58] Fig. 57 is a diagrammatic representation of an embodiment analogous to [Figure 54] Fig. 53, but in which it will be seen that, by inverting the bellow ends on which the arms are fixed, a movement is obtained in the opposite direction to that in [Figure 54] Fig. 53.

Referring to [Figure 59] Fig. 58, this shows an assembly of two individual implants, of which the left-hand implant [20'] includes two end pieces 21', 22' which are able to move in the continuation of one another, with interposition of a deformable element 23' analogous to the deformable element 4'. The ends 24' and 25' of the pieces 21', 22' have fixation holes enabling anchoring means, for example pedicle screws to be secured. In contrast to the representations in the preceding figures, these fixation means at the ends 24', 25' do not necessarily permit a pivoting of the pedicle screws, such as the screws 10' and 11', and by contrast they can be formed by bores or eyelets which permit rigid connection without any possibility of pivoting of the screw relative to its corresponding end 24' or 25'.

The right-hand implant 26' also has two end pieces arranged in the continuation of one another, namely 27' and 28', of which the ends 29' and 30' are analogous to the ends 24' and 25' so as to receive the pedicle screws without any possibility of movement of the screw relative to the end which bears it. The end piece 27' has, starting from the end 29', a part in the form of an elongate threaded rod which terminates in the movable part of a deformable hydraulic element 32' analogous to the element 23' or to the element 4'. It will thus be appreciated that if the deformable element 32' deforms and provokes a relative movement, for example of spacing apart or distraction, between the pieces 27' and 28', the movement of the piece 27' relative to the piece 28' will provoke the rotation of the piece 27' on account of the fact that its threaded rod moves in the fixed nut 31'. The result of this is that the end 29' is driven relative to the end 30' in a displacement movement simultaneously of translation and rotation. Consequently, the end of the pedicle screw (not shown) borne by the piece 29' of the movable piece 27' will describe a helical movement whose axis is formed by the alignment of the pieces 27' and 28'.

If the two elements 20' and 26' are connected as is shown in the figure, by a valve 13' in a line 12', it will be appreciated that, as in [Figure 51] Fig. 50, the reduction in the volume of the movable element 23' will translate into an increase in the volume of the movable element 32' and, thus, of the opposed axial displacements of the implants [20' and 26'], with, in addition, the movement of rotation of the piece 27'.

Reference is now made to [Figure 60] Fig. 59. In this figure, the element [20'] 23' is

identical to that in [Figure 59] Fig. 58. Like the implant 26', the other implant 33' has an end piece 28' terminating in an end 30' which permits the fixation and blocking of an anchoring screw. By contrast, the element 33' includes a second end piece 34' with its end 35' for receiving and blocking the anchoring screws, this piece 34' being connected to the element 28' in such a way as to be immobilized in translation but free in rotation about the axis of the piece 34'. The movable part 36' of the deformable element 39' has a piece in the form of a tapped nut 37' through which a threaded part 38' of the piece 34' passes. It will thus be appreciated that when the deformable element 39' deforms, the movement of the movable piece 36' will provoke a rotation of the end piece 34' about its axis, but without translation relative to the end piece 28', in such a way that the end 35' turns without displacement in translation relative to the end 30'.

In the embodiment shown in [Figure 60] Fig. 59, by virtue of the valve 13', a variation in the volume of the deformable element 20' will translate into an inverse variation in the volume of the deformable element 39', in such a way that the lengthening of the element 20' translates into a rotation of the end 35' in one direction, whilst the shortening of the element 20' produces a rotation of the end 35' in the opposite direction.

Of course, all the other control combinations can be realized, for example in the case of [Figure 59] Fig. 58, in order to provoke identical lengthening of the elements [20' and 26'] 23' and 32' while ensuring the rotation of the piece 27'.

Referring to [Figures 61 and 62] Figs. 60 and 61, embodiments of the implant 26' in [Figure 59] Fig. 58 are shown. It will be seen that the end pieces [25'] 27' and 28' have a streamlined shape in the form of a dolphin's snout and have transverse passages forming the ends 29' and 30' and permitting the fixation of a pedicle screw in an entirely traditional manner. In this figure, the portion forming the nut 31' is borne by the lower piece 27'. This nut 31' is traversed by a threaded rod 40' which is rigidly supported by the upper end piece 28' in such a way that the axial displacement of this rod provokes the rotation of the piece 28' relative to the piece 27'. The threaded rod 40', as will be seen in [Figure 62] Fig. 61, passes into a pot 41' which is received in a leaktight manner inside the hydraulic bellows 32' acting as movable element, and the rod 40' can turn in this pot about its axis while being retained inside the pot by a securing ring 42'. It will be seen from this that it is also possible to give the overall implant an elongate streamlined shape particularly appropriate for good cohabitation with the surrounding tissue.

Referring to [Figure 63] Fig. 62, this shows an embodiment of an implant 33' according to [Figure 60] Fig. 59 with an upper end 28' and a lower end piece 34' which has arms 43' ending in a bearing 44' inside which there can freely turn, while being retained axially by a securing ring 45', a threaded rod 46' which is integral with the piece 28' and is capable of turning inside a nut 47' of a pot 48' fixed in a leaktight manner on the metal bellows 49' at the end integral with the end piece 34'. It will be appreciated that any



movement of the bellows provokes an axial movement of the nut 47', which provokes a rotation without axial movement of the piece 28' relative to the piece 34'.

We now describe the use of a double implant for the correction of scoliosis in a patient having an angle of scoliosis  $a_1$  between the two scoliotic vertebral stages. During the operation, the surgeon employs traditional means to establish a preliminary correction bringing the angle of scoliosis to the value  $a_2 < a_1$ . He then places the two individual implants on either side of the vertebral column between the two vertebral stages in question, with the valve 13' open, which permits the shortening of one of the individual implants and the compensating elongation of the other individual implant, and he fixes the two elements with the aid of their pedicle screws. It then suffices to re-close the valve 13' so that the two individual implants are blocked in their position without any possibility of movement and they maintain the scoliotic part of the vertebral column in the angle  $a_2$ . From this moment onwards, all the loads are borne by the prosthesis constituted by the double implant.

After a reasonable postoperative period during which the stresses are supported essentially by the prosthesis, the neutral point of the vertebral column will adapt by virtue of the reorganization of the skeletal and paravertebral tissues, and this will reduce the load on the prosthesis in the standing position. It is possible either to estimate this reduction in load or to provide the prosthesis with pressure sensors which can be interrogated, preferably noninvasively, as is already well known, and which will indicate that the vertebral column has reached a state of equilibrium.

A new adjustment will then be made by asking the patient to bend sideways to reduce the value of the angle  $a$  of scoliosis to a value  $a_2 < a_1$  after opening the valve 13', which renders the two implants movable. Once this angle  $a_2$  has been obtained, the valve is closed again so that the two implants maintain this new position and prevent the return to a greater angle of scoliosis. This blocking of the prosthesis causes the patient the sensation of an obstacle which will gradually disappear until such time as a new equilibrium is found.

By means of a succession of these [manoeuvres] maneuvers, it is thus possible to reduce or even eliminate the angle of scoliosis and to remove the prosthesis.

It will be appreciated that the same principles can be used for gradually re-establishing kyphosis or lordosis by using pairs of implants which are arranged, for example, in accordance with the figures.

Likewise, by using a pair of prostheses as in [Figure 9] Fig. 9, for example, it would be possible to gradually reduce kyphoscoliosis.

[Figure 64] Fig. 63 shows a transverse cross section of an implant in a refined embodiment of the invention.

This implant 1' includes two parts in the form of end pieces 51' and 52' in the shape of a dolphin's head, having at their outermost parts holes or eyelets 53' and 54' through which it is possible to engage pedicle screws whose heads can be fixed rigidly in the area of the

holes 53', 54'. Alternatively, these holes can be arranged in such a way as to permit an articulation of the head of the pedicle screw and thus an angular displacement between the end element and the screw which it bears.

Arranged between the two end pieces 51' and 52' there is a third piece 55' which is movable relative to the two ends. The piece 55' has a stirrup shape, of which one of the branches 56' supports a metal bellows 57' in a leaktight manner, the free end of which bellows is fixed in a leaktight manner against a piece 58' which is able to slide relative to the stirrup 55' and bears, in the manner of a journal, by virtue of a securing ring 45', but axially nonmovable relative to the piece 58', a threaded rod 59' which passes through a complementary tapped hole of the second branch 60' of the piece 55'. It will thus be appreciated that when the deformable element constituted by the bellows 57' deforms, the thus provoked axial displacement of the rod 59' integral with the upper end 52' entrains the rotation of this rod 59' in the fixed nut formed in the branch 60', and consequently a simultaneous movement of translation and rotation of the end piece 52' relative to the piece 60'.

Arranged inside the end piece 51' is a leaktight cavity 61' which serves as a high-pressure chamber and in which there is a bellows 62' which is hermetically sealed and in which a vacuum has been established. The stiffness of this bellows, however, is sufficient to ensure that it tends spontaneously to deploy and increase in volume even when it is surrounded by high pressure prevailing in the chamber 61'. The chamber 61' communicates via a nondeformable conduit 63' with the inside of the metal bellows 57' by way of a high-pressure valve 64' lodged in the branch 56'. This valve 64' has a tubular slide of soft iron 65' which is normally held back by a spring in the position closing off the passage towards the bellows 57'. It will be appreciated that when the plunger core 65' is brought into a position of opening counter to the valve spring, liquid at high pressure in the chamber 61' will run along the conduit 63' and enter the bellows 57'. The high pressure in the chamber 61' is maintained by the concomitant deformation of the sealed bellows 62'. This inflow of liquid provokes the displacement of the piece 58' towards the branch 60' and, consequently, the distraction and rotation of the end piece 52' relative to the central piece 55'.

The inside of the bellows 57' also communicates, by way of a low-pressure valve 66' equipped with a plunger core identical to the core 65' situated in the piece 58', with the volume 67' surrounding the various pieces contained inside the deformable impermeable sleeve 68', at the two ends of which the ends of the pieces 51' and 52' emerge, this volume 67' forming the low-pressure volume. It will be appreciated that when the valve [66] 66' is opened, liquid contained in the bellows 57' will exit and spread through the low-pressure volume 67', thus permitting a retraction or compression of the bellows 57' and a simultaneous rotation of the piece 52' in the opposite direction.

The high-pressure reservoir [61] 61' is recharged by way of a metal bellows 69' which

is of a diameter substantially smaller than that of the bellows 57' and which is interposed between the pieces 51' and 55'. When the pieces 51' and 55' move away from each other, this bellows 69' expands and aspires liquid from the low-pressure chamber 67' by way of a nonreturn valve 70'. By contrast, when the pieces 51' and 56' close together, the high pressure generated in the bellows 69' causes liquid at very high pressure to enter the high-pressure chamber 61' by way of a nonreturn valve 71'.

It is not necessary for the deformation of the bellows 69' to be of a great amplitude; on the contrary, it is preferable for the gap between the piece 51' and the piece 56' to be small and for the course of oscillation between the pieces 51' and 55' to be limited, a multiplicity of oscillations, for example, as the subject walks or changes position of his/her body sufficing to generate the high pressure permitting supply to the chamber 61'.

In such an embodiment, as long as neither of the valves 64' and 66' is open, the two pieces 51' and 52' can move relative to one another only by a very short distance, and this thus ensures that the two skeletal elements to which they are anchored, for example two vertebrae, are maintained in the chosen position. The device for establishing high pressure can even be used to obtain a certain viscous damping of the small displacements permitted between the pieces 51' and 55'.

It will also be appreciated that having arranged the high-pressure and low-pressure valves 64', 66' on either side of the bellows 67', one or other of these valves can easily be actuated, according to choice, for example by a strong magnet placed on the skin in line with one of the valves in order to attract the ferromagnetic plunger such as 65' towards the left of the drawing and to open the valve.

It will of course be appreciated that it would be possible to form an implant analogous to that which has just been described, but arranged so as not to provoke rotation between the two end pieces, but simply a movement of distraction or compression. It would also be possible to form an implant such as that in [Figure 13] Fig. 13 using most of the structural arrangements in [Figure 14] Fig. 14 so as to form an implant uniquely with rotation.

By combining with an implant of this type a joining rod analogous to the rods 7', and by forming at the ends of the pieces 51' and 52' articulation bearings permitting a pivoting of the pedicle screws relative to the said ends, it is also possible to form implants according to [Figures 51, 52, or 55, or 56] Figs. 50, 51, or 54, or 55.

In the case where use is made of a large number of implants according to the invention arranged along the vertebral column between different levels of the spine, it is also possible to provide a single high-pressure reservoir and a single low-pressure reservoir as well as a single deformable element for establishing high pressure, this reservoir assembly being arranged away from the various individual implants and being connected to each of these by a low-pressure conduit and a high-pressure conduit, the implants themselves in this case not having any hydraulic deformable element other than the motor bellows acting as bellows 57'.

Also, the controllable valves, such as the valves 13', 19' or 64' or 66', instead of being controlled directly by way of a ferromagnetic plunger capable of being attracted by a magnet placed on the surface of the skin near the valve, could be controlled, in a hydraulic manner known per se, by a small pilot valve which is easier to actuate because it has a plunger of lower inertia, the pilot valve addressing a control pressure to the actual switching valve in order to open the latter, and the closure of the pilot valve, by contrast, provoking the closure of the main valve.

It will also be appreciated that it is possible to limit the movement of one of the ends relative to the other by providing traditional abutment means between the two pieces, which come into force if the travel of the deformable member or of the motor bellows exceeds a desired amplitude. Thus, this provides an element of safety in the case of a fault in the functioning of the implant which prevents it from exactly maintaining the desired position, for example escape of liquid or conduit deformation or excessive deformation of a bellows.

The implants according to the invention are preferably delivered with a temporary removable element which holds them in a position of desired spacing between the two end elements and which the surgeon removes once he has fitted the implant and fixed the pedicle screws or other anchoring means at the ends of the implant.

The invention also relates to a therapeutic surgical procedure for modifying the position of two portions or elements of the skeleton, for example two vertebrae, in which procedure at least one implant element according to the invention is fitted, one of the ends is fixed by an anchoring means to one of the portions or elements of the skeleton, and the other end is fixed by an anchoring means to the other portion or element of the skeleton, if appropriate after having carried out a preliminary correction of the relative position of the [said] two portions or elements, the approach route and the tissues operated on are left to heal, then, preferably by noninvasive control means, a corrective displacement or force is produced causing corresponding stressing of the two end pieces of the implant, or the anchoring means, relative to one another.

This displacement can be provoked directly by the patient's body and, in this case, the displacement is permitted by permitting deformation of the movable element, for example a hydraulic bellows, then, when the displacement has been completed, all subsequent displacements are prohibited by blocking the [said] deformable element.

In another embodiment, in order to provoke the displacement, a deformation of the movable element is temporarily provoked by applying a force with which it is possible to obtain the desired displacement, after which the movement of the deformable element is once again blocked and prevented.

In a third embodiment, by contrast, the movable element is allowed to exert a permanent force, preferably constant or possibly progressively variable, between the two ends and thus the two portions or elements of the skeleton, with an intensity of force which

is insufficient to provoke an abrupt modification of dimension and an attack on the tissue opposing this dimensional variation, but which is sufficient to provoke, as is known per se in the field of surgery, a slow deformation and an adaptation of the various tissues until the desired corrected position is reached.

Such a procedure is particularly suitable for correction of scoliosis or kyphoscoliosis.

When a force is exerted between two skeletal elements by means of an implant according to the invention, this force can advantageously be from a few daN to 25 or 30 daN.

The device can advantageously include force or pressure sensors for limiting or regulating the force to be exerted. Such miniaturized sensors are available on the market.

It has been seen that the noninvasive control means can be magnets which, from outside the body, can displace or attract a ferromagnetic mass, such as a valve slide, counter to a spring or an elastic return means which brings the mass back to its initial position once the magnet has been removed.

It is also possible to use an external device which creates a magnetic or electromagnetic rotary field which, inside the body, turns a rotary piece, for example a rotary slide of a valve.

[This application is based upon the French Patent Applications No. 96 09157, filed on July 22, 1996, and No. 98 05549, filed on April 30, 1998, the disclosures of which are hereby incorporated by reference thereto in their entireties and the priorities are hereby claimed under 35 USC 119.]